99-045-1

MVP Laboratories, Inc.
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'99 AUG 16 P12:00

August 10, 1999

Regulatory Analysis and Development
PPD, APHIS, Suite 3C03
4700 River Road Unit 118
Riverdale, MD 20737-1238

RE: Docket No. 99-045-1, Guideline on Good Clinical Practices, VICH Topic GL9

Dear Sir or Madam

MVP Laboratories, Inc., is a manufacturer of veterinary biological products and hold a current U.S. Veterinary Establishment License. We offer the following comments to Docket 99-045-1 regarding guidelines on Good Clinical Practices VICH Topic GL9:

GENERAL COMMENTS:

This guideline is obviously intended to serve both FDA for studies involving pharmaceuticals and additives, and VS for efficacy and field safety studies of biologics. In fact, FDA has published a similar request for comments regarding this same VICH document. A large share of the guideline applies only to pharmaceuticals and additives and does not apply to safety and efficacy studies of biologics.

SPECIFIC COMMENTS:

2.7. Should replace "...in accordance with the concepts of good manufacturing practice (GMP)" with "...in accordance with the requirements of the relevant regulatory authority". "GMP" is presently an ill-defined term with no consensus regarding its meaning.

3.1.2. It may not always be possible in smaller firms to have a separate investigator and monitor for all studies.

3.1.3. For licensed firms, an APHIS Form 2007 should suffice for this requirement.

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3.2.1. This would not be applicable if the investigator is an employee of the sponsor, which will be the case in most biologics studies.

3.2.13 This would not be applicable if the animal owner and sponsor are the same as is often the case in efficacy studies.

3.2.16 Again, would not be applicable if investigator is employee of sponsor.

5. A monitor may not be required if investigator is employee of sponsor, as is often the case in biologics studies.

6.3.11.1 – 6.3.11.5 This information appears to be intended for nutritional or pharmaceutical products and is not needed for most field safety and immunogenicity tests for biologicals.

6.3.12.1 – 6.3.12.6. This information appears to be intended for nutritional or pharmaceutical products and is not needed for most field safety and immunogenicity tests for biologicals.

7.1.2 Should specify this does not apply to preliminary research studies.

7.2.3.2. Seems redundant if documents, data and reports are initialed and dated as they should be.

7.3.6.2.1. This information appears to be intended for nutritional or pharmaceutical products and is not needed for most field safety and immunogenicity tests for biologicals.

7.3.6.2.3. In efficacy and field safety tests, "condition's" are not being treated. These tests are conducted in normal animals. Again, this describes pharmaceutical tests.

7.3.6.3.1 and 7.3.6.3.2: This information appears to be intended for nutritional or pharmaceutical products and is not needed for most field safety and immunogenicity tests for biologicals.

7.3.6.6. This information appears to be intended for nutritional or pharmaceutical products and is not needed for most field safety and immunogenicity tests for biologicals

7.3.10 3 "Audit certification" is not defined. Clarification is needed.

8.2.2.2. This information appears to be intended for nutritional or pharmaceutical products and is not needed for most field safety and immunogenicity tests for biologicals

8.2.2.4. This information appears to be intended for nutritional or pharmaceutical products and is not needed for most field safety and immunogenicity tests for biologicals.

Because so much of this guideline refers to pharmaceuticals and nutritional products, we would prefer to see either 1) a guideline specific to biologics, or 2) a VS Memo outlining how this guideline will be interpreted regarding biologics (in effect, a VS guideline for the VICH guideline)

Thank you for the opportunity to comment on this docket.

Sincerely,

Jack D. McGonigle
Mgr QC/Reg. Affairs

cc: M.L. Chapek, President